SmartPA Criteria Proposal

Drug/Drug Class:	Diacomit Clinical Edit
First Implementation Date:	January 30, 2020
Revised Date:	November 19, 2020
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Diacomit® (stiripentol)

Why Issue Selected: In August 2018, the FDA approved Diacomit® (stiripentol) to be used in combination with clobazam for treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. Dravet syndrome is a rare genetic condition that appears during the first year of life with frequent fever-related seizures. Later, other types of seizures typically arise, including myoclonic seizures. Additionally, status epilepticus, a potentially life-threatening state of continuous seizure activity requiring emergency medical care, may occur. Approximately 80% of children with Dravet syndrome have a pathogenic variant in the SCN1A gene. Children with Dravet syndrome typically experience poor development of language and motor skills, hyperactivity and difficulty relating to others. Dravet syndrome has a higher mortality rate than other types of epilepsy, with most deaths occurring before 10 years of age. Dravet syndrome is estimated to appear in 1/15,700 births in the United States, or 0.0064% of the population. First line therapies for Dravet syndrome include clobazam, valproic acid, and cannabidiol. Diacomit is different from other seizure agents in that possible mechanisms of action include not only direct effects mediated through the gamma-aminobutyric acid (GABA)A receptor but also indirect effects involving inhibition of cytochrome P450 activity with resulting increases in blood levels of clobazam and its active metabolite.

Program-Specific Information:

Date Range FFS 4-1-2019 to 3-31-2020				
Drug	**Claims**	**Spend**	**Cost per unit**	**Cost per month**
Diacomit 250mg capsule	1	$1,509.55	$25.00 WAC	$3,750.00 WAC based on 25kg patient at 50mg/kg/day
Diacomit 500mg capsule	0	-	$50.00 WAC	
Diacomit 250mg packet	3	$6,028.65	$25.00 WAC	
Diacomit 500mg packet	1	$3,009.55	$50.00 WAC	

Type of Criteria:
☒ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Diacomit® (stiripentol)
- Age range: All appropriate MO HealthNet participants aged 2 years and older

Approval Criteria

Initial Therapy:

- Participant aged 2 years or older **AND**
- Documented diagnosis of Dravet syndrome **AND**
- Concurrent use with clobazam **AND**
- Documented trial of valproate (defined as 30 days ~~**in the past year**~~) **AND**
- Documented trial of Epidiolex (defined as 30 days ~~**in the past year**~~) **AND**
- Documented trial of clobazam (defined as 30 days ~~**in the past 60 days**~~) **AND**
- Prescribed by a neurologist or other appropriate specialist **AND**
- Documentation of baseline neutrophil and platelet counts **AND**
- **Documentation of baseline seizure frequency and duration**
- Initial approval of prior authorization is 3 months

Continuation of Therapy:

- Renewal of prior authorization may be up to 6 months following documentation of the following:
  - Concurrent use with clobazam **AND**
  - **Documentation of therapy meeting the goals of therapy AND**
  - **Documentation of reduced seizure burden or improvement in quality of life using a validated scale for the disease state AND**
  - ~~**Lack of ADE/ADR to therapy AND**~~
  - Complete blood count with differential required every 6 months

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Claim exceeds dosage limitations:
  - 360 capsules or packets for the 250mg strengths every 30 days **OR**
  - 180 capsules or packets for the 500mg strengths every 30 days

Required Documentation

Laboratory Results:	X	Progress Notes:	X
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

6 months

References

- Diacomit [package insert]. France: Biocodex; August 2018
- National Organization for Rare Disorders (NORD). Dravet Syndrome. https://rarediseases.org/rare-diseases/dravet-syndrome-spectrum/. Accessed April 16, 2020.
- IPD Analytics Rx Insights_Epilepsy – New and Emerging Treatments for Dravet Syndrome and Lennox-Gastaut Syndrome. May 2019.
- IPD Analytics Rx Insights_New Drug Approval_Diacomit (stiripentol). September 2018.
- Cross, J H, et al. Dravet syndrome: Treatment options and management of prolonged seizures. Epilepsia. 2019;60(S3):S39–S48. DOI: 10.1111/epi.16334